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A Case Study:

Can 3D printers be used to address the prosthetic needs of amputees in the Dominican Republic?

By

Adriana Coll De Peña

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science in Science, Technology, and Public Policy

Department of Public Policy College of Liberal Arts

Rochester Institute of Technology Rochester, NY August 5th, 2020 A Case Study:

Can 3D printers be used to address the prosthetic needs of amputees in the Dominican Republic?

By

Adriana Coll De Peña

A thesis proposal submitted to the Public Policy Program at Rochester Institute of Technology in partial fulfillment of The Science, Technology & Public Policy Master's Degree

College of Liberal Arts/Public Policy Program at ROCHESTER INSTITUTE OF TECHNOLOGY

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ABSTRACT

With a history of recurring occupations and dictatorships, the development of the Dominican national infrastructure has been heavily interrupted by continuous transfers of power. As a result, the lack of a lean government structure is evident when studying the national healthcare system. Despite numerous organizations and agencies overseeing the needs of amputees across the country, only about 347 of the estimated 5,350 new amputees receive prosthetics per year (ARS Humano Salud, 2020; Asociación Dominicana de Rehabilitación, 2018, 2019). Although the needs of this large underserved population are not being met, the implementation of more cost-effective 3D printing technologies seems difficult and distant. This study explores how the Dominican national infrastructure affects the healthcare and wellbeing of amputees, the local economic viability of 3D printers to manufacture prosthetics, and the hurdles that may be encountered in the implementation of such technology across the country. Ultimately, the goal of this study is to determine whether the Dominican Republic is ready for a paradigm shift in its medical technology, and what policy changes would be required for this to happen. While limited research has been conducted in the area, it is believed that a paradigm shift of this nature could result in benefits not only for the amputee population but also for society.

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1. Introduction

The Dominican Republic has been the subject of numerous invasions, as late as the U.S. occupation of 1965-1966 (Roorda et al., 2014). Located in a key geographical location within the Caribbean, the country has one of the fastest economic growth rates in Latin America becoming the leader of the Caribbean economy (Barghini, 2019; The World Bank, 2020). As a result, the Dominican Republic, with a history of colonization followed by rapid economic growth, experienced a delayed and improvised development of its national infrastructure, leaving deeply rooted issues that are still evident today. One of the more evident issues was the creation of parallel government agencies and institutions with overlapping agendas. A clear example of this can be witnessed in the redundancy of medical and social services agencies, which repeatedly tends to prevent people from receiving the care they need. Amputees constitute one of the many underserved populations that, despite the best intentions of the government, are left unattended. Despite the emergence of more cost-effective technologies that could address the needs of these populations, several issues in the medical and social services infrastructure current cost and labor-intensive technologies from being replaced.

With a population of 10.5 million people, there are an estimated 350,000 amputees in the country, most of whom have not received proper care (Central Intelligence Agency, 2020; García Chaljub, 2017). Given that the national demand is not being met, 3D printed prosthetics will be presented as a more economically viable alternative to traditionally manufactured prosthetics. The 3D printing technology has revolutionized many fields, including the medical field by providing fast and inexpensive alternatives for orthopedic support systems, medical tools, and surgery practice models, among others (Dally et al., 2015; Kumar Malyala et al., 2017; Pavlosky et al., 2018; Portnova et al., 2018; Zuniga et al., 2015). Another key advantage of using 3D printed products is

that they can be easily modified to meet the needs of its users. Thus, this study aims to analyze how the national infrastructure combined with the medical and social policies affect the health care of amputees in the country, as well as the benefits of the implementation of more efficient prosthetic manufacturing technologies.

Moreover, while maximizing the efficiency of budgets is a goal shared by all countries, over the past decade there has been a difference of one and a half orders of magnitude between the healthcare spending per capita of high- and low-income countries (World Health Organization, 2017). In 2015, high-income countries had an average per capita healthcare spending of \$4,874.90 while low-income countries had an average per capita spending of \$233.51 (World Health Organization, 2017). In 2014, Dominican Republic was reported to have spent an average of \$580 per capita in healthcare (World Health Organization, 2018). Considering the low political feasibility of significantly increasing the national healthcare spending, the added economic strain faced by developing countries further increases the need for efficiency (Nah & Osifo-Dawodu, 2007; O'Donnell, 2007). This work proposes the exploration of more cost-effective technologies to maximize the impact of the resources and more effectively address the needs of amputees in the country.

1.1 SOCIAL BACKGROUND AND SIGNIFICANCE

Given the current global amputee population, estimated to be around 10 million people, it is of great importance to address the needs of this underserved population (LeBlanc, 2008). When amputees do not receive the proper care they require, not only does it cause severe repercussions in the life of the patient, but it can also trigger several societal consequences. These consequences include but are not limited to discrimination, abuse, and long-term economic burdens for both the State and the family of the patient. A key point to note is that despite several agencies being

responsible for the care of amputees in the Dominican Republic, there is only one organization providing physical rehabilitative care for low-income patients. As a result, the percentage of patients that can receive prosthetics is limited to about 6.5% per year, or 347 out of the estimated 5,350 new amputees (ARS Humano Salud, 2020; Asociación Dominicana de Rehabilitación, 2018, 2019).

Similar to most developing countries, amputations in the Dominican Republic are mainly caused by trauma related to traffic accidents and by improper or delayed diabetes medical care. With poorly maintained vehicles and roads, the government reported that 10,092 people were injured in traffic accidents in 2018 (Oficina Nacional de Estadística, 2018). Moreover, despite prevention being the most cost-effective approach long-term, most medical practices focus on treating diseases, especially in developing countries where public healthcare funding is limited, and prevention becomes a luxury. An estimated 74% of the Dominican population receives some degree of coverage or subsidy through the national health insurance, however, due to the low national income, even subsidized healthcare expenses can be out of reach for the less privileged (ARS Humano Salud, 2020; Superintendencia de Salud y Riesgos Laborales, 2020). As a result, while diabetes-related amputations take place across the globe, the incidence of preventable amputations is greater in developing countries, leading to poorer clinical outcomes and higher economic costs (Apelqvist & Larsson, 2000). Hence, this study aims to identify potential solutions to meet the needs of amputees while taking into account the social and political context in the country. The hurdles identified in this study not only affect the implementation of 3D printed prosthetics in the Dominican Republic but could be extended to any population whose needs are not being met due to outdated medical technology.

1.2 MOTIVATION

Despite the paradigm shift suggesting there is an increased interest in both disability medicine and innovative medical technologies, first-hand experience has taught me differently. In 2018 I was the project leader of a small team trying to bring 3D printers to a non-governmental organization (NGO) in the Dominican Republic. The team was a joint effort between two international NGOs, a physician, and a researcher, all of whom had worked in similar projects in the past. The main goal of this project was to implement 3D printer technologies at the NGO to alleviate the economic burden it faced from the manufacturing of prosthetics using the traditional method. Although the proposed shift in technology from the traditional manufacturing method to the 3D printer approach was economically sound, the project fell through due to lack of a suitable environment for its implementation. In this case, professionals showed resistance to change stemming from the limited scientific and technical knowledge, training, and experience in the field. However, this experience made me realize that the limited education was only part of the issue. In hindsight, the main flaw of the project had been attempting to address the needs of amputees directly at the NGO level when in reality this should be treated as a national issue. When the needs of a significant portion of the population are not being met, it is the responsibility of the government to take action. Even in the case where the original project had been successful, this success would have been short lived without the support from governmental policies that promote an environment that is suited for the implementation of emerging technologies. Despite providing the organization with training during the early stages of the implementation, without a local database and proper continuous training, the technology would have been likely to fail. Therefore, rather than proposing a change at an organization level, this study focuses on the potential implementation of 3D technologies at a national level with policy support to maximize the effect of the resources available.

2. HISTORY OF THE NATIONAL MEDICAL AND SOCIAL INFRASTRUCTURES

To fully understand the hurdles in the implementation of an emerging technology in Dominican Republic, the reader needs to understand the history of the country and the events that led to the development of its current infrastructure. To set the context for the development of the national medical and social infrastructures, the following section provides an overview of the history of the country and its policies related to the topic.

2.1 THE INDEPENDENCE ERA

Upon obtaining independence from Spain and then from Haiti in the early to mid-1800s, the Dominican Republic was a poor country lagging in terms of development and infrastructure when compared to other countries in the region (Roorda et al., 2014). This short-lived independence was once again interrupted from 1861-1865 by a pact made with the Spanish crown that reverted the colonial status of the country following numerous blood-shedding Haitian invasions (Eller, 2017).

After years of civil unrest and political turmoil, during the last two decades of the century dictator Ulises Heureaux had a vision of progress for the infrastructure of the nation at the cost of driving the economy deep into debt (Roorda et al., 2014). However, as the national economy kept weakening, much of the limited funding was instead routed for personal purposes or to support his nation-wide police vigilance and espionage system, limiting the reach of his vision (Haggerty, 1989). In the following years, government bonds were sold to foreign financial institutions, in particular British institutions, to remediate the economy.

Meanwhile, as U.S. interest in Cuba and the Caribbean increased, an American financial institution acquired the Dominican government bonds, increasing their stake in the country and region. Thus, an increase in corruption and national debt combined with the heightened American interest led to

the first American intervention in 1916. Throughout this invasion, one of the main goals was to reform and re-envision the infrastructure of the country for the convenience of the U.S. (Tillman, 2016). The U.S. successfully proclaimed the establishment of a military government that acted by force and served the interests of the Dominican elite. Despite attempts to improve the social system of the country, the main contributions were the centralization of the military and extending road access to all regions of the country (Stanton, 1985). However, during this military government, as early as 1917, all sessions of the Dominican Congress were suspended, limiting any lasting benefit that came during the military leadership. Then, after a brief succession of presidents and with the support of the American government, Rafael Leonidas Trujillo, known as one of the most atrocious dictators in the Americas, rose to power.

2.2 THE TRUJILLO AND POST-TRUJILLO ERAS

During his dictatorship from 1930-1961, Trujillo attempted to nationalize enterprises; however, much of his efforts were diverted into passing bills and making contracts that would benefit private enterprises, including his own. To a great extent, Trujillo treated the State as a personal enterprise, making him the owner of the main income generators of the nation including the mines, sugar cane, tobacco, and coffee fields, among others. As a result of this monopoly in both power and enterprises, the country was managed without protocols, checks, or balances, generating a lack of transparency that would outlast his dictatorship.

This accumulation of publicly unopposed power, however, was also what allowed Trujillo to make major contributions to the infrastructure of the country. In 1956, he made the most significant contribution to the national public health system to date through the Public Health Trujillo Code (Código Trujillo de Salud Pública) of 1956, also known as Ley No. 4471 (*Código Trujillo de Salud Pública*, (*Ley No. 4471*), 1956). In fact, many of the articles included in the Trujillo Code still

remain in effect and were not revised until several decades later. Through this code, he established the national public health system, created preventative medicine networks, and improved hospital infrastructure, among other valuable benefits to the national health system. Similar improvements were also made in different fields, including early contributions to what would decades later become the Dominican Social Security System. While his contributions to the national infrastructure are still evident in the current system, his State of tyranny came to an end in 1961 upon his assassination.

After decades of oppression, the end of his regime served to awaken the Dominican population. Upon his death, the inefficiency of several government programs and the uneven distribution of power among its citizens came to light, drawing increased scrutiny (Wiarda, 1968). Unfortunately, his contributions to the national infrastructure were not the only aspect of his regime that outlasted him. The fragmentation caused by the Trujillo regime among the population and political parties is attributed as one of the main factors that led to the revolution and civil war of 1965. Following the war, as the country tried to slowly recover from its fresh wounds, the legitimacy of its leadership was often questioned leading to great distrust among the people (Wiarda, 1968).

2.3 THE MODERN ERA

After a bloody and interrupted path towards actual independence, the Dominican Republic started consolidating its efforts and prioritizing the needs of its people. The major sign of this transition was the passage of the bill Ley No. 87-01 in 1987 (*Ley No. 87-01 Que Crea El Sistema Dominicano de Seguridad Social*, 1987). The two main outcomes from this bill, with respect to this study, were the establishment of the Dominican Social Security System (Sistema Dominicano de Seguridad Social, SDSS) and the national health insurance (Seguro Nacional de Salud, SENASA) both of which will later be discussed in more detail. Prior to the establishment of a national comprehensive

medical insurance, the only option for the less privileged uninsured people was to seek care at substandard hospitals with limited resources, many riddled with rats and frequent power outages.

Leonel Fernández served as the president of the Republic for three terms (1996-2000, 2004-2008, 2008-2012). During his presidencies, for the first time, the country adopted a modern approach to government, institutionalizing the different sections of the government and passing a bill that laid out the strategy for the national development. After years working on the bill, the government and its officials finally integrated it into the Constitution in 2010, establishing a clear path with specific goals in every area (*Ley No. 1-12 Que Establece La Estrategia Nacional de Desarrollo*, 2010). In addition to attempting to improve the efficiency of the government, one of the main objectives of this bill (Objective 2.2) was to have a system that guarantees the right to health and social services to its citizens. It emphasized the need to guarantee access to proper health services to everyone in the country by solidifying and strengthening the resolutions of the Ley 87-01, fortifying the SDSS and increasing the coverage of SENASA. In addition, Objective 2.2.3 of Ley 1-12 aims to guarantee the social services and medical needs of people with disabilities, which complements the contributions made in Ley 87-01.

In parallel, between the first and second terms of presidency of Leonel Fernández, Hipólito Mejía held presidency from 2000-2004. During his term he aimed to improve the health and social services in the country. As one of his first actions, Mejía signed a decree, Decreto No. 741-00, that established the Office of the First Lady as a technical and administrative office of the government with functions and responsibilities (*Decreto No. 741-00*, 2000). The main goal of the office was to develop and promote projects that would emphasize growth in the areas of education, women, family and sustainable development; since then, raising awareness and supporting people with disabilities has been one of the main contributions of the office.

Despite the historic view of people with disabilities as "burdens" to the State and to their families, in recent years the Dominican Republic began addressing these needs by focusing its medical and social efforts on the needs of traditionally marginalized populations. As part of the most recent efforts from the government to provide inclusive services to its people, in 2013 the Office of the First Lady inaugurated the Comprehensive Care Center for Disability (Centro de Atención Integral para la Discapacidad, CAID) in the capital. The mission of the CAID is to help in the evaluation, diagnosis and rehabilitation of children up to 10 years old by bringing the best physicians across the countries and using cutting edge technologies in the field (Centro de Atención Integral para la Discapacidad, 2019). After the inauguration and early success of the first center, three more CAID centers followed in different cities in the years 2015, 2016, and 2019, suggesting an increased interest in providing both disability medicine and innovative medical technologies. While long-standing organizations such as the Asociación Dominicana de Rehabilitación have focused on providing disability care prior to the establishment of CAID, since this is not a governmental initiative, details regarding this organization are discussed later in the study.

3. LITERATURE REVIEW

An extensive literature review was conducted to ensure that 3D printing was a viable alternative to the current traditional method of manufacturing prosthetics. Given that 3D printing has not been implemented in the medical field in the Dominican Republic, the focus of the review was to evaluate the success of 3D technologies in the medical field, particularly in the manufacturing of low-cost prosthetics. However, because a great percentage of the implementation of these devices comes from the work of NGOs and other voluntary projects, the formal research available online does not accurately represent the current state of the technology. For this reason, some of these anecdotal testimonies were included in the literature review to set a more accurate framework of

the current situation. The lack of information available online further supports the need for the work presented in this study.

3.1 APPLICATIONS OF 3D PRINTERS IN THE MEDICAL FIELD

Since most papers were related to the medical applications of 3D printers, this category was redefined to non-prosthetic applications of 3D printers in the medical field. These applications were included in the literature review to show other areas of the medical field where this technology has been successfully implemented. Moreover, given that the hurdles in the implementation of 3D technologies is a national issue, it was important to show some of the other applications from which the country could benefit upon its implementation.

Despite the early signs of potential, 3D printing had somewhat of a slow start resulting from the elevated costs and limited product availability. However, the recent increase in accessibility to 3D printing technologies have lowered the overall operational cost and increased public interest in the technology (Portnova et al., 2018). As a result, the introduction of 3D technologies in the medical field has shown great promise with applications ranging from implants to surgical instruments. Product availability and supporting technologies have also increased greatly. One such example is the availability of optical and laser 3D scanners, which provide an attractive cost-efficient alternative to the previous scanning methods (Golovin et al., 2018). As a result of more 3D scanning methods becoming available and the integration of additive manufacturing in the field, professionals can now design their own devices directly on the digital scans (Dessery & Pallari, 2018).

He et al. (2014) studied the potential of desktop 3D printers in the fabrication of low-cost soft prostheses (He et al., 2014). To do this, they followed the method known as a Scanning Printing Polish. Upon scanning the area of interest, an ear, they were able to design and print a negative

replica mold. Silicon was then cast onto the mold and upon curing the soft ear prosthesis was removed from the mold. In this study, the authors reported that the main advantages of 3D printing were the reduction of cost from the traditional prosthesis fabrication method, and the endless amount of shapes that can be made using this approach.

Printed products can be used directly as a support system as well. Portnova et al. (2018) published a study in which they designed an open wrist-driven orthosis (WDO) for people with spinal cord injuries (Portnova et al., 2018). In the case of individuals with spinal cord injuries, these patients are often given metal WDOs to assist their hand function. The device proposed by Portnova et al. (2018) provided a low-cost and light-weight device that decreased fabrication time and provided patients with improved functioning for activities of daily living (ADL). Moreover, as a result of the decreased cost and fabrication time, this study provides a more accessible device that can be used in low-resource settings.

The surgical field is another area that has experienced a surge in the medical application of 3D printers. One such application, as studied by Marconi et al. (2017), is in pre-surgical preparation by providing medical students, radiologists, and surgeons with 3D printed anatomical models reconstructed from Multiple Detector Computed Tomography images (Marconi et al., 2017). To assess their success, they analyzed the changes in pre-surgery preparation time needed by the users. Overall, the study showed that the use of the models led to a decrease in time needed to assess the subject, accompanied by an increase in the understanding of the subject. Similarly, Mukherjee et al. (2017) made 3D models based on computed tomography (CT) scans to provide a more thorough pre-surgical planning for complex BoneBridge cases (Mukherjee et al., 2017). Overall, from the 16 cases studied, surgeons believe the models helped them choose better implants, increase the placement accuracy, and reduce operating time.

In their study, Kumar Malyala et al. (2017) used CT scans coupled with patient-specific computer-aided designs (CAD) and additive manufacturing to develop a basal osseointegrated implant (Kumar Malyala et al., 2017). One of the key features emphasized by Kumar Malyala et al. (2017) is the ability to plan the surgery and develop implants based on the 3D CAD models that are specific to the anatomical features of the patient. As a result, the group saw deceases in surgery time and blood loss, as well as an increase in patient outcome, which can reduce the financial burden on the healthcare providers.

The manufacturing of high quality, low cost, open access tools, such as the stethoscopes made by Pavlosky et al. (2018) in their study, is another application of 3D printers in the medical field (Pavlosky et al., 2018). Despite acknowledging that under certain scenarios, lower quality devices may be acceptable due to the lack of better alternatives, they successfully developed a design that did not trade-off quality for price. These results were promising as the skills used to fabricate these stethoscopes could be translated to development of different types of medical equipment.

3.2 Use of 3D Printers to Manufacture Low-cost Limb Prosthetics

Despite first emerging over three decades ago, the technology did not start thriving across the world until the cost of 3D printers and their associated materials lowered. As a result of the new affordability and availability, the potential of 3D printing technology in the healthcare industry has also seen an exponential increase, raising special interest in developing countries where resources are more limited (Ibrahim et al., 2015). Unfortunately, limited accessibility to prosthetics is not restricted to developing countries. In countries like the U.S. where the cost of medical services and products has been inflated by the hybrid healthcare and medical insurance system, people of low resources and children are the most affected. The same applies to war-affected regions. Thus, this

section will study low-cost prosthetics that could be used or have been used in developing countries given that the need for low-cost alternatives is universal.

Dally et al. (2015) studied the requirements for a low-cost 3D printed hand prosthesis for developing countries (Dally et al., 2015). In particular, they discuss the feasibility and practicability of an open-source hand design with individualization potential. Upon testing models of different sizes, their largest and smallest versions were not able to perform adequately, making them inadequate for adults in low-resource areas. However, based on their findings, they believe their design is a valid option for children as they would still be able to perform well in their everyday tasks and in case of breakage, the pieces would be easily replaced.

In their study, Gretsch et al. (2015) developed a 3D printed prosthetic arm for people with transradial amputations. Some of the key advantages of their design included the individual movement of the thumb, the ability to hold objects with all five fingers, and the weight of the device. Moreover, the family of the 13-year-old who tested the device also emphasized that the low \$300 price tag would also allow them to upgrade the hand and socket as the patient grew older. This last point also brings to light one of the main advantages of using 3D printed prosthetics, which is the ability to replace an individual part of the device if it breaks or to modify sections as the anatomy of the users change.

Zuniga et al. (2015) developed a prosthetic hand for children with limb deficiencies, called the Cyborg beast (Zuniga et al., 2015). Zuniga et al. (2016) then followed up with the study and conducted a thorough assessment of the performance of the device before and after 6 months of usage (Zuniga et al., 2016). While the study concluded that the Cyborg beast seems to be fit for children, they recommend that certified prosthetists and healthcare professionals should be

involved in the development of the devices given the lack of standards currently required for these devices. Upon expanding on the knowledge gained by the hand prosthesis, Zuniga et al. (2017) developed a low-cost prosthetic for children that included the shoulder, arm and hand (Zuniga et al., 2017). Through taking advantage of the customizability of 3D printed devices, the group was able to adjust the weight of the protheses, leading to improved posture, which led to improvements in functional balance and spinal deviation.

Now, focusing on adult devices, Ariyanto et al. (2017) developed a 3D printed low-cost anthropomorphic hand using an external gear motor (Ariyanto et al., 2017). Some of the key characteristics of this device were the two joints in each finger and the seven grip patterns, which enhance the performance in ADL. Using these characteristics, the hand could successfully hold objects of different sizes and shapes, and was able to pass their writing test on a white board.

Motivated by the prevalence of limb loss in war-affected regions, Alkhatib et al. (2019) conducted a thorough analysis of flexible joints to develop a 3D printed prosthetic hand (Alkhatib et al., 2019). Considering the social stigma faced by amputees in low resource settings, their design was met with enthusiasm. They believe that their contribution has implications for a more robust design as they were successfully able to design a device whose joints performed similar to the human joints.

Triwiyanto et al. (2020) developed an open source 3D printed prosthetic hand that used electromyography signals to control the hand via linear actuators (Triwiyanto et al., 2020). Despite the addition of the electrical component, they were still able to develop a low-cost device, at \$472, within the accepted weight. Currently, their device can use the EMG signals to control grasping and opening the hand, but in the future, they hope to integrate more movements. They also note

that the activity of the EMG signals can be affected by physical conditions, which is a factor that cannot be ignored.

Mohammadi et al. (2020) developed a multi-articulating soft 3D printed robotic prosthetic (Mohammadi et al., 2020). In this study, the group exploited the advantages of monolithic 3D printing, which allowed them to design a low weight device with membrane enclosed joints. At a \$200 mark, this device was successfully able to perform three different grasps types with a high power-grip force and a fast finger flexion speed. This sophisticated design is available online and was developed as a low-cost alternative for people in developing countries or with economic disadvantages.

While there has been an increase in research published on the development of 3D printed upper-limb prostheses, there is very limited work on the development of lower-limb devices. Previously, given the high load exerted on lower-limb prostheses, the limited directionality of the 3D printer nozzle prevented the successful development of these devices. However, with the recent advancements in 3D technology, there has been an increase in successful projects. In fact, some of the most successful and promising projects have been shared in news articles and magazines over the past few years.

A collaboration between Thinking Robot Studios Inc. and some NSCAD professors led to the design and development of a leg prosthesis for an alumni (3D Systems, 2014; Gregurić, 2019). Inspired by a 3D-printed mask from a New-York based designer, the patient helped design the external part of the device. In just 17 days from the first meeting, the group was able to design and develop a working prototype that the patient was able to use. One of the highlights for the patient was the ability to customize her prosthesis into something beautiful.

In Japan, the start-up SHC Design Inc. is producing low-cost custom-made 3D printed limbs (Fujikawa, 2016). While the company is still in its early stages, they are hoping to bring the cost of a lower-limb prosthesis down from its current cost in Japan, which is about \$4,200, to \$100 per device. While in the country insurance tends to cover the price of prosthetic legs, the high price tag makes it difficult for people to have specialized devices for different occasions. In this article they discuss a 41-year-old patient who lost his right leg upon birth and received a free device after working part time for the company. The patient was particularly happy to be able to wear sandals with the device thanks to the natural look of the limb and the gap left between the first and the second toes to accommodate alternative footwear. At the time, this company was the closest to releasing to fully 3D printed legs into the market. They were hoping to sell their printers and software for about \$2,000 excluding the scanner.

In 2017, the first entirely 3D printed prosthetic leg in the United Arab Emirates was developed to help a British expat who had tragically lost her leg during a horse riding accident (Webster, 2017). The project was sponsored and facilitated by the joint forces of Dubai Health Authority, Arab Health, Prosfit, Mecuris and Mediclinic as part of the 3D Khair initiative. An amputee for over 10 years, the patient had experience with different high-end custom-made prostheses, yet after a few days of wearing the new device, she was very satisfied with the product. One of the main advantages shown in this project was the ability to design a first-time fit of the socket thanks to the scanning and design techniques used in the 3D printing of prostheses.

In addition, Goldstein et al. (2019) successfully developed an amphibious 3D printed lower-limb prosthetic that allowed its users to smoothly transition between land and water (Goldstein et al., 2020). Unlike its counterparts, while this design mainly focuses on providing a suitable alternative to devices used by lower-limb amputees to swim, this one allows users to walk on solid ground.

This study mainly presented as a pilot study recommends that further research should be conducted prior to drawing major conclusions.

Nia Technologies Inc., a Canada-based NPO, focuses on the development of partially 3D printed lower limb prosthetics and ankle-foot orthosis (Nia Technologies Inc., 2018). With the collaboration of researchers from the University of Toronto, Nia developed a toolchain that includes all the steps necessary to manufacture a prosthetic or orthotic device, which includes the scanners, software and printers. A key characteristic that distinguished Nia is that in addition to designing their devices, they also research, test and evaluate them with a focus on children in developing countries. With their approach, they are able to reduce the manufacturing of devices from five days to one and a half compared to the traditional method without sacrificing the quality. While a specific value was not found for the reduction in cost, it is also reported that there is a significant cost decrease associated with this approach. These observations further support the benefits of adopting 3D technologies as it suggests that even hybrid approaches will result in both manufacturing time and cost reductions.

It should be clear from these sources that 3D printed prosthetics offer a low-cost alternative to traditionally manufactured prosthetic devices. The use of 3D technologies allows to fabricate prosthetics at significantly lower costs with advantages to the patient, such as reduced device weight and user-customizability. Combined, the low cost and flexibility of these devices makes them ideal for use in developing countries. The following section will discuss the successful implementation of 3D technologies in the neighboring Haiti.

3.3 HEALING HANDS FOR HAITI

Despite the differences in culture and government structure between Haiti and Dominican Republic, being developing countries, the neighboring nations face similar socio-economic and healthcare issues. Thus, as part of this review, Haiti provides an example of a developing country that has been successfully able to implement 3D printers to manufacture upper-limb prostheses.

In 1999, the non-profit organization Healing Hands for Haiti (HHH) was founded with the goal "to deliver quality, sustainable physical medicine and rehabilitation education, training and care for the people of Haiti" (Healing Hands for Haiti, 2010). In 2015, the Enable Community Foundation, also known as Limbforge, received a \$600,000 grant from the Google Impact Challenge for Disabilities ("Google.Org Launches \$20 Million Google Impact Challenge: Disabilities," 2015). With this grant, the organization and its partners provided the funds to create a 3D Print Center at HHH and covered the costs of technology training for its clinicians (Victoria Hand Project, 2019). In 2016 Victoria Hand Project (VHP) partnered with the Enable Community Foundation (ECF). As a result of their joint effort, dozens of prosthetic devices have been manufactured and provided to Haitians in need. In addition, VHP and collaborating researchers from RIT continue to conduct periodic training workshops for HHH personnel and interested partners at the HHH facilities in Port-au-Prince. Through the years, ECF, VHP and collaborating researchers from RIT have paid several visits to the center and have kept working in the improvement and diversification of the prosthetic devices available at the center.

A key aspect in the success of 3D printed prosthetics as mentioned by most studies is the need for prosthetists to ensure that no harm will come from the devices. Thus, acknowledging the lack of engineers at small clinics and considering the novelty of 3D printers, the goal was to set up a system that did not require an engineering background and was mostly autonomous. In 2018,

Myers (2018) conducted a study where she assessed the process of teaching two non-engineers prosthetists from HHH how to design and fabricate prosthetics using 3D scanning and printers (Myers, 2018). Overall, she determined that despite the increased time requirements needed by non-engineers to learn how to manipulate the software, the training was successful, and the effort put in by the users led to great reward.

In addition to the center in Haiti, VHP is also associated with other organizations in Guatemala, Nepal, Cambodia, Ecuador, Egypt, Uganda and Kenya to provide prosthetics to people in need. These serve as additional examples of countries that have been successful at implementing 3D technologies in the manufacturing of prosthetics. However, it is also important to note that in these examples NGOs are providing local services to amputees while this study focuses on the implementation of these technologies at a national scale. Moreover, despite the best efforts to give autonomy to HHH, it still relies on the feedback of its external collaborators. The goal of this study is to develop a fully independent system that is only dependent on the Dominican government, empowering the local community not only with the technology but also with the knowledge that comes with it. Therefore, while this model cannot be directly translated into the Dominican healthcare system, it does provide an example of a model that has shown success in other developing countries.

3.4 ASOCIACIÓN DOMINICANA DE REHABILITACIÓN

A key characteristic in the physical rehabilitation field in Dominican Republic is that there is virtually a single organization, governmental or non-governmental, in charge of providing physical rehabilitative care for low-income patients in the country, the Asociación Dominicana de Rehabilitación (ADR). This section serves to set the background of the ADR, which will be crucial in the understanding of the prosthetic health care for amputees.

number of people in need of physical rehabilitation. To address this unmet need, Mrs. Mary Perez de Marranzini founded the non-governmental, non-profit organization Asociación Dominicana de Rehabilitación (ADR) in 1963 with the help from personal and governmental donations (Asociación Dominicana de Rehabilitación, n.d.). Over half a century later, the role played by the ADR in the physical rehabilitation industry has only increased as reflected by its nationwide presence with 34 centers across the country. The centers focus on a combination of the special programs of physical and rehabilitative medicine, school of special education, training, and job placement. The number of services and treatments provided by the ADR has been at a constant increase over the past decades, going from 1.09 million services in 2016 to 1.37 million services in 2018, increasing by 20% in two years (Asociación Dominicana de Rehabilitación, 2017, 2019). As a physical rehabilitation center, the ADR offers services that range from the manufacturing and fitting of prosthetic and orthotic devices to providing different physical rehabilitation treatments. As a result of its crucial role in society, the ADR has become the organization that receives the largest yearly donation the central government gives to any non-profit in the country (Dirección General de Presupuesto, 2020). With an annual budget of \$17.5 million, 11% of the income of the ADR comes from the Central Government and the Dominican Presidency, while the rest comes from both public and private institutions (Asociación Dominicana de Rehabilitación, 2019). However, it must be noted that in addition to monetary funding, the government also provides assistance to the ADR in the form of policies and personnel, among others (Asociación Dominicana de Rehabilitación, 2019; Fajardo Gutiérrez, 2020). Despite being an NGO, the interconnection between the ADR and the government in terms of rehabilitation care at a national scale makes this organization relevant in both governmental and non-governmental healthcare

After the polio epidemic of the fifties, the Dominican Republic was not equipped to assist the large

contexts. Thus, any changes that take place in the prosthetic health care of amputees require a combined effort between the government and the ADR.

4. RESEARCH QUESTIONS

The main purpose of this thesis is to assess why the prosthetic needs of amputees in the Dominican Republic are not being met and present an economically viable alternative that could maximize the efficiency of the available resources. In this case, 3D printed prosthetics are evaluated as the alternative to the current traditional manufacturing technique. Upon determining whether this technology is an economically viable solution, the hurdles in the potential implementation of 3D printed prosthetics will be assessed. This analysis will be conducted and evaluated from economic, social and political contexts to determine whether implementation of the emerging technology of 3D printed prosthetics may provide a sound solution for the prosthetic provision in the Dominican Republic. To do this, this study will attempt to answer three research questions:

- 1. Why are the prosthetic needs of amputees in the Dominican Republic not being met?

 The purpose of this question is to analyze the current state of the prosthetic health care for amputees hoping to find the root of the issue. Ultimately, the goal is to use these findings to provide well-founded policy recommendations.
- 2. Are 3D technologies a more economically viable alternative to manufacture prosthetics in the Dominican Republic?

The purpose of this question is to establish whether 3D printed prosthetics are an economically viable alternative to the current traditional manufacturing technique that is being employed in the country. Given the economic burden of the current manufacturing technique, finding a more economically viable alternative could significantly increase the

yearly prosthetic yield. The technique was chosen as it has shown success in similar settings as supported through the findings presented in the Literature Review.

3. What would be the main challenges in the implementation of 3D printed prosthetics in Dominican Republic?

The purpose of this question is to analyze the challenges that may be encountered upon implementing 3D printed prosthetics in the country. Through these findings, the goal is to provide practical guidance for the potential implementation.

5. METHODS

5.1 STUDY DESIGN AND DATA COLLECTION

For this case study, a wide array of information was needed from both online sources and direct contact via e-mail or telephone with the different government and medical agencies involved. Overall, the data consisted of the organizational charts of different Dominican government agencies, the budget of the medical organizations relevant to the study, policies regarding healthcare coverage for amputees, and the costs related to the traditional and the 3D printed-based methods. Most information regarding government agencies, medical organizations, and laws related to this study was readily available on their websites or in other online publications. However, when the data of interest was not available online, people from the respective agencies were contacted for guidance and information. Additionally, experts in the field were also contacted for input and guidance. Given that the information collected was public information, no formal approval was needed for the study.

Research Question 1 assesses why the prosthetic needs of amputees in the country are not being met. To address Research Question 1, information on the current state of the health care of

amputees was collected from different government institutions, which will described later, and was revised with experts in the field. To expand on the search, the different agencies that are responsible for amputee health care in the country were studied from their government-owned website and by contacting them directly. Then, information regarding the actual production and coverage of prosthetics was collected from the NGO Asociación Dominicana de Rehabilitación (ADR), which is the only organization in the country producing prosthetics for low-income amputees. The expected prosthetic production and coverage based on policies was then compared to the actual prosthesis output from the ADR. Based on this information, two experts in the field were contacted to further assess the cause of the discrepancy between the expected and actual prosthesis care and connect it back to the medical and social infrastructure in the country. The first expert in the field was Dr. Buenaventura García Chaljub, who has been a physical rehabilitation physician in the country for the past twenty-five years (García Chaljub, 2020). In addition to his strong rehabilitative medicine background, he has held administrative positions at public hospitals in which he was part of the bridge between policies and patient care. The other was Dr. Juliana Fajardo Gutiérrez who has a background in Occupational Health and has vast experience in the reform and modernization of the health field (Fajardo Gutiérrez, 2020). In addition, she holds several academic degrees related to health care, including a post-graduate degree in the Techniques of Development Management and Administration of Program Politics and Social Projects, among others.

Research Question 2 aims to determine whether 3D printed prosthetics are an economically viable alternative to the current method. This question was addressed by conducting a Cost-Effectiveness Analysis (CEA) method, which assists in the decision-making process by giving a quantitative value to each component of the study to make a monetary comparison between two methods. The

costs of the traditional method were obtained from the ADR, both through their website and via e-mail. The costs associated with the 3D printer-based method were obtained by contacting two experts in the field and from literature. Here, the experts in the field were Jade Myers, who was a key contributor and researcher in the development of the 3D printing center at the HHH, and Michael Peirone, the Chief Operating Officer of VHP (Myers, 2020; Peirone, 2020). Both experts have vast experience in 3D printed prosthetics and have worked in collaboration with HHH for years.

Research Question 3 focuses on the main hurdles that would be encountered upon the implementation of the 3D printer-based method in the Dominican Republic from a social and political standpoint in order to evaluate the practical feasibility of the switch in technologies. To assess the social and political contexts of such an implementation, a consultant for both private and public health and non-health related projects, Hinya De Peña, and the former Director General for the Dominican General Directorate of Internal Taxes, Guarocuya Félix, were consulted (De Peña, 2020; Félix, 2020). Additionally, information about the challenges in a social context were included from literature and personal experience. The personal experience in this scenario is based on visiting both the HHH and the ADR, and contacting several experts in the field over the past three years across different countries.

6. FINDINGS

6.1 Why are the prosthetic needs of amputees in the Dominican Republic not being met?

The organizational chart in Figure 1 summarizes the relationship between the different entities involved in the prosthetic health care of amputees in the Dominican Republic. This chart uses information gathered through conducting research online using the different government websites

and contacting several of the agencies directly to ask for additional information regarding the main actors in the health care for amputees. Two experts, Dr. García Chaljub and Dr. Fajardo Gutiérrez, helped to refine the information regarding the agencies involved in the process. The information presented below regarding amputee health care and the barriers to health they may encounter was also obtained in the same manner. It must be emphasized that this is not an organic organizational chart of the government, but rather a functional organizational chart based on the role that the different institutions play in the health care of amputees. As seen in Figure 1, while the Central Government and the Presidency of the Republic (Presidencia de la República) function as hierarchically superior entities, dashed lines are used to show that all institutions are autonomous. Among the institutions involved, there are two ministries, the Ministry of Labor (Ministerio de Trabajo) and the Ministry of Public Health (Ministerio de Salud Pública), two National Councils, the National Social Security Council (Consejo Nacional de Seguridad Social, CNSS), and the National Council on Disability (Consejo Nacional de Discapacidad, CONADIS), and four additional governmental entities, the National Health Insurance (Seguro Nacional de Salud, SENASA), the Superintendence of Health and Occupational Risks (Superintendencia de Salud y Riesgos Laborales, SISALRIL), the Dominican Institute for Prevention and Protection of Occupational Risks (Instituto Dominicano de Prevención y Protección de Riesgos Laborales, IDOPPRIL), and the National Health Service (Servicio Nacional de Salud, SNS). Despite not being a government institution, the ADR was also included in the chart as it is the sole provider of prosthetics for the low-income population in the country. While private health insurance companies also play a key role in the national health care system, upon contacting them it was determined that the majority of amputations go through the public system, via SENASA or public hospitals in general. The two main private health insurances in the country are ARS Humano Salud

with 1.6 million affiliations, and ARS Palic Salud with 0.9 million affiliations. However, over 80% of those with private health insurances are also covered by the national public health system under the social security plan. Therefore, considering the preventability of a high percentage of the amputations and the high correlation between low-income and amputations, while acknowledging the role of the private institutions, this study will focus on the public health system.

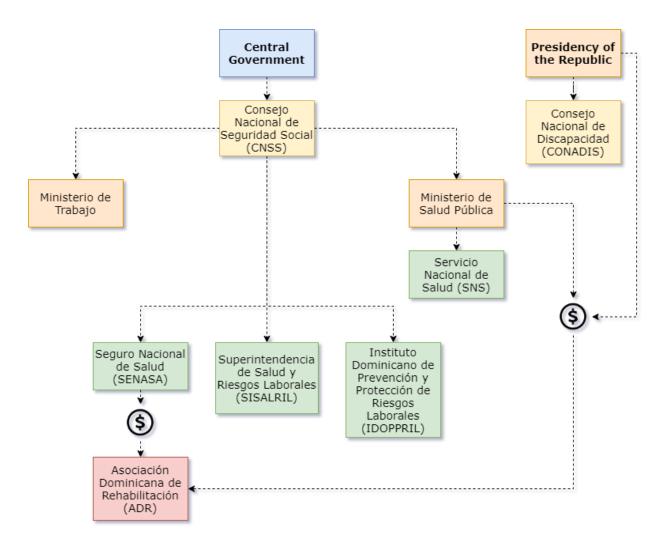


Figure 1. Diagram representation of the different organizations and institutions involved in the healthcare for amputees. The arrows represent their relationship to the central government and to each other. Dashed lines were used to indicate autonomous institutions, and the "\$" sign was used to reflect funding.

Generally, ministries do not fall under the jurisdiction of a council, however, under the framework of amputee health care, the Ministry of Labor and the Ministry of Public Health serve as administrative entities within the CNSS. SENASA, SISALRIL and IDOPPRIL resulted from a resolution passed by the CNSS. This resolution was passed under Ley No. 87-01, which created the Dominican Social Security System (Ley No. 87-01 Que Crea El Sistema Dominicano de Seguridad Social, 1987). Similarly, the SNS resulted from a resolution passed by the Ministry of Health. Based on the agreement established by the resolutions that created each institution and on the information provided by the institutions, CONADIS, CNSS, SISALRIL, IDOPPRIL and SNS were made responsible for the administrative and political aspect of the passage of bills and decrees that establishes the health care rights of amputees. On the other hand, SENASA, the national health insurance, establishes the official coverage list and is responsible for paying the health care providers, in this case the ADR. In recent years, SENASA adjusted its requirements to include unemployed people, which has allowed it to offer some degree of coverage or subsidy to 74% of the population through the social security plan and occasionally in conjunction with private health insurances (ARS Humano Salud, 2020; Superintendencia de Salud y Riesgos Laborales, 2020). However, due to the novelty in the changes in requirements, the country is currently undergoing a transition and a high percentage of the low-income unemployed population is still in the process of acquiring the subsidized national health insurance. As a result, 20% of the population does not have any type, public nor private, of health coverage (ARS Humano Salud, 2020).

Nonetheless, the experience of the patients is vastly different from what is suggested by the regulatory agencies and the organizational chart. There are generally three main steps in the health care of amputees; the amputation (except for congenital cases), the prosthesis and the rehabilitation. Amputations are generally covered by SENASA and are treated at trauma and

private hospitals in the case of accidents and at hospitals specializing in diabetes for diabetic foot. The uninsured can receive amputations at low costs or free of charge at public hospitals. However, not all hospitals that perform amputations have physical rehabilitation personnel and surgeons often perform their amputations without consulting prosthetists rendering a high percentage of amputations non-suited for prosthetics. Then, upon being discharged from the hospital, patients do not receive any structured guidance on seeking prosthetic and rehabilitative care, and must seek it on their own initiative (Fajardo Gutiérrez, 2020; García Chaljub, 2020). The ones who inquire are pointed towards the ADR and learn that despite the coverage catalogue of SENASA indicating an almost full coverage of prosthetics, these refer to endoprostheses. Unlike limb-prostheses, endoprostheses are prostheses that are placed inside the body. Thus, to get the cost of a limbprosthesis covered by SENASA, patients are required to submit several medical forms of which hospitals are generally unaware, making it difficult for patients to obtain them. As a result, only a limited number of patients get their devices covered by SENASA. Another group of patients that are able to obtain coverage for their prosthetic expenses are those who acquire their injuries in the workforce, which makes them eligible for coverage based on SISALRIL and IDOPPRIL policies. Unfortunately, there are currently no established systems for uninsured patients to obtain prosthetic care without paying out-of-pocket.

The ADR subsidizes part of the cost of the devices to its patients; however, the current technology employed at the center relies heavily on expensive resources and the patient co-pay might still be elevated. Additionally, the production cost of a prosthetic is around \$1,350, thus the number of devices the ADR can subsidize is also limited considering that prosthetics are only one of the hundreds of services that are offered at their centers. To put the cost of a device into perspective, the yearly per capita gross domestic product at purchasing power parity (GDP at PPP) in the

country is \$17,000 (Central Intelligence Agency, 2020). Lastly, even when patients obtain a device, the care, replacement costs and high likelihood of prosthetic misfit can also prevent patients from continuing their use.

Moreover, in addition to considering the monetary barrier present in the prosthetic health care of amputees, the transportation barrier is another key element affecting amputee health care in the country. In developing countries where a higher than usual percentage of the population lives paycheck to paycheck, missing work to attend a medical appointment can be difficult, particularly when the patient does not have access to transportation. In fact, in the case of lower limb amputations, even if the patient has access to some type of public transportation, they might be unable to use these services because of their physical limitations. The barrier created by limited transportation is further exacerbated by the number of in-person visits required by the traditionally manufactured prosthetic fabrication method. Traditionally, this method requires the patient to undergo formal scans, the creation of a mold around the amputated limb, the fabrication of the device, and the in-person fitting. Unfortunately, the first fit is generally not a good match and further modifications need to be made requiring the patient to return.

Despite having 34 centers across the country, based on economic constraints, the ADR only offers prosthetic care at their one center in the capital. Depending on the city of origin of the patient, the journey to the capital can take up to 8 hours using public transportation, which may not be accessible for the people with lower limb amputations. Thus, despite its numerous centers, the lack of centers offering prosthetic care makes the transportation barrier even more significant under the present context. As a result, only about 347 of the estimated 5,350 new amputees receive prosthetics every year (ARS Humano Salud, 2020; Asociación Dominicana de Rehabilitación, 2018, 2019).

At first glance, it seems that the prosthetic needs of amputees in the country are not being met due to the monetary and transportation barriers. However, upon further analysis it appears to lie in the infrastructure of the healthcare system presented in Figure 1. Despite numerous governmental institutions overseeing the health care of amputees, this redundancy has ultimately led to the dilution of responsibilities among the different regulatory institutions, in addition to drawing funds away from the cause. For instance, the National Council on Disability, CONADIS, which should be the key advocate for amputees in the country, does not fund nor advocate for amputee health care. SENASA offers coverage for the amputation but not for limb-prosthetics unless thorough medical documentation, which is not easily accessible, is provided. The Ministry of Public Health and the SNS do not have a consolidated effort to address the needs of amputees. As a result, there is not a single national protocol for the health care of amputees, and the government efforts are dispersed and inefficient. These findings were corroborated and confirmed by Dr. García Chaljub and Dr. Fajardo Gutiérrez. The dilution of the amputee health care responsibilities across the numerous actors involved has also led to a dilution in accountability, rendering it difficult to address the issue without changing the governmental approach first. Moreover, the dilution of the instructional responsibility also became evident while conducting research for this study. Upon contacting the institutions involved in the health care for amputees, several of them automatically referred any inquiries to another institution, ultimately generating a loop. Similarly, the dilution in accountability is also expressed by the lack of a plan in motion on behalf of government institutions to address the needs of populations such as amputees. Despite the needs of numerous underserved populations not being met, no official reports are generated regarding the current state of their health or potential plans to remediate the situation.

Furthermore, the dilution of responsibilities in the health field does not only affect the amputee population, as people do not know what agency to turn to when facing health issues. Figure 2 is a screenshot of a tweet posted on the personal Twitter account of Chanel Mateo Rosa, the director of the SNS, which further highlights the general unawareness of the national health among the public. The message translates to: "If you know someone who for whatever reason needs an orthopedic surgery and has not been able to get it because they do not have a health insurance or the insurance does not cover the osteosynthesis materials please write to crosa@sns.gob.do" (Mateo Rosa, 2020). Followed by a comment that translates to: "The Dominican State will cover the surgery and materials through @SNSRDO. RT would be appreciated." Note that "@SNSRDO" refers to the official SNS Twitter account. While this tweet may seem anecdotal, it reflects the limited communication across the health care institutions in the country and between the institutions and the people. It must be emphasized that this tweet was not part of an information campaign but a sole effort to promote this information from the personal account of the director of the SNS. Despite the best efforts, this approach is particularly ineffective considering that a significant percentage of the people living in the outskirts of the cities and in smaller villages are functionally illiterate or have limited access to electronic communication devices (De Peña, 2020). As a result of the lack of a clear leader in the disability health care for amputees, the ADR has become the main advocate for this population. However, and with its limited resources and NGO status, its actions can only go so far.



Figure 2. Screenshot of tweet posted by the director of the SNS, Chanel Mateo Rosa, from his personal, public account. In the post, he urges to spread the word to anyone in need for orthopedic surgery and cannot afford it as the surgery costs and materials will be covered by the government through the SNS (Mateo Rosa, 2020).

While at first sight the monetary and transportation barriers appear to be the reason for the lack of prosthetics, it ought to be highlighted that the main issue is the source of these barriers, which in this case has been lack of government efficiency and institutional accountability. The ADR has limited funding for prosthetic care, which creates both a monetary and a transportation barrier as, under the current circumstances, it cannot afford to provide prosthesis services at numerous centers. Meanwhile, a redundancy in government agency has led to institutional inefficiency and a high percentage of funding covering redundant administrative fees rather than covering health care fees. Thus, the dilution of responsibility stemming from the institutional redundancy has left the amputee population, among others, vastly unattended.

6.2 Are 3D technologies a more economically viable alternative to manufacture prosthetics in the Dominican Republic?

As discussed in previous sections, the prosthetic needs of amputees in the Dominican Republic are not being met, and despite the underlying root stemming from the governmental infrastructure, the main barriers to care appear to be monetary and transportation. To address the monetary barrier, a CEA will be performed, as this method has been proven to be a good tool in the decision-making process. The goal of this analysis is to estimate whether the 3D-printer based method would be more economically viable than the traditional method in the fabrication of prosthetics.

Assumptions

First, to properly address the issue, certain assumptions ought to be made. Since the goal is to present a more economic fabrication alternative that will allow patients to obtain the devices free of cost, all costs associated with fabrication will be considered costs and the prosthetics will be considered a transfer of wealth in the form of a donation to the patient. To remove any bias introduced into the economy by the COVID-19 pandemic, the values that were obtained in Dominican Pesos (DOP) were converted to U.S. Dollars (USD) using the average 2019 conversion rate. Based on the official Ministry of Economy, Planification and Development report, the conversion rate was determined to be 51.33 \$DOP to \$USD (Ministerio de Economía, Planificación y Desarrollo, 2020). Upon converting the currency, the analysis will be conducted in real USD based on the assumption that the cost of the major components of the analysis have a constant value in real dollars. A discount rate of 4.2% was estimated by subtracting the 2019 inflation rate from the Ministry of Economy, Planification and Development from the 2019 Dominican Federal Bank (Banco Central de la República Dominicana) interest rate (Banco Central de la República Dominicana, Planificación y Desarrollo, 2020).

This discount rate will be applied throughout the study to convert future costs into the 2019 net present cost (2019).

The lifespan of the traditionally manufactured prosthetics at ADR is about 2.5 years with minor repairs along the way (Asociación Dominicana de Rehabilitación, 2020). While there is limited data from HHH to determine the lifespan of prosthetics analogous to the ones that are being presented in this study, from the 32 devices that have been made over the last five years, three devices have returned to the clinic for repairs. Considering that transportation is a very significant barrier in Haiti and people may not have been able to return for repairs, despite the suggested longer lifespan of the 3D printed devices, it will be assumed that the lifespan of the devices from both technologies is the same. Moreover, it must be noted that for both technologies, fluctuations in weight due to pregnancy, illnesses, or natural causes, may result in the need for a new device. As a result of the device lifespan and fluctuations in patient weight, it must be noted that the 347 devices per year do not necessarily go towards new patients every year. The space requirements for the 3D printer-based center are less than for the traditional manufacturing center and the ADR currently has the space needed for a 3D printer-based center, therefore space requirements were neglected from the study. Similarly, for simplification purposes, the electricity costs of both methods will be excluded, although it should be noted that the traditional method is more electricity-intensive. Lastly, a major assumption that is made is that this project would be developed in partnership with an NGO such as VHP. This assumption was made because bringing an organization with significant experience in the field across different developing countries would be beneficial by providing training directly relevant to the setting and the software and system that they use. While software could be purchased separately, these organizations have developed a system that facilitates the design portion of the prostheses. Without the use of this system, the

training and software requirements of the center would be higher, and the likelihood of success reduced, hence the need for this assumption.

<u>Traditional Manufacturing Center Expenses</u>

The costs of this method were obtained from the ADR annual report online and by contacting the organization directly. Considering that the expenses related to the set-up of the center took place in the past and that much of the equipment resulted from donations, the set-up costs of the center will be neglected from the analysis. Considering the great variance in complexity and cost from one prosthetic to the next, an average cost of \$1,150 will be used for the materials cost of a prosthesis, determined by obtaining the percentages and number of each kind of prosthesis fabricated by the ADR and comparing it to their cost (Asociación Dominicana de Rehabilitación, 2020). To put the cost of a device into perspective, the yearly per capita gross domestic product at purchasing power parity (GDP at PPP) in the country is \$17,000 (Central Intelligence Agency, 2020). The indirect costs for this method, as given by the ADR, range between 10-15%, therefore an average of 12.5% will be used for the analysis (Asociación Dominicana de Rehabilitación, 2020). These costs include administrative fees, one visit for measurements, the manufacturing of the device, one visit for fitting, the fixing of the device, and one visit for fitting and placing the device. The unit cost of the materials and indirect costs per device will then be multiplied by the amount of prosthesis currently being fabricated by the ADR, which is 347 per year (Asociación Dominicana de Rehabilitación, 2019). At this time, the ADR is not able to provide their yearly reparations cost. While in reality the reparation costs for the traditional method tend to be much higher than for the 3D-based method, for the sake of the analysis the values were set equal to each other at \$937.50 per year. The origin of this value will be explained in more detail during the 3D Printer-based Center Expenses section. Upon combining the costs, as seen in Table 1, the

production and maintenance costs at the ADR were estimated to be approximately \$450,000 per year.

Table 1. Estimated yearly production and maintenance costs for the traditional center with a fabrication of 347 devices.

Traditional Center	Amount	Unit Cost		Total Cost	
Yearly Production and Maintenance Costs					
Materials/prosthetic	347	\$	1,150.00	\$	399,050.00
Indirect costs/prosthetic	347	\$	143.75	\$	49,881.25
Repairs	1	\$	937.50	\$	937.50
Total Cost			\$	449,868.75	

3D Printer-based Center Expenses

The costs of this method were obtained from the experts in the field, Jade Myers and Michael Peirone, both of whom have extensive experience in the field (Myers, 2020; Peirone, 2020). The general training costs are around \$1,600 per person, but an additional \$400 per person were included to cover the expenses of the person giving the training. The amounts in Table 2 reflect set-up costs for a single center with the equipment to print approximately 347 devices per year at normal capacity. As seen in Table 2, the estimated expenses associated with the set-up costs of the 3D printer-based center were approximately \$29,000.

Table 2. Estimated set-up costs for a 3D printer-based center with the equipment to print approximately 347 devices per year at normal capacity.

3D Printer-based Center	Amount	Unit Cost		Total Cost		
Set-up Costs						
3D Printers	5	\$ 3,000.00	\$	15,000.00		
3D Scanning Equipment	2	\$ 1,600.00	\$	3,200.00		
Computer	1	\$ 850.00	\$	850.00		
UPS Power Supply	1	\$ 175.00	\$	175.00		
Training/person	5	\$ 2,000.00	\$	10,000.00		
Total Cost			\$	29,225.00		

Generally, a 2.3 kg roll of 3D printing filament prints 3-4 upper limb prosthetics, but information was not found regarding the lower limb prosthetics requirement, thus it was assumed that a roll can yield two lower limb prosthetics. To ensure this assumption would not affect the outcome of the analysis, a sensitivity analysis was performed on the average device yield per roll. This analysis showed that the outcome of the overall comparison between the expenses associated with each fabrication method would not be affected by changes in yield. Using the percentages of prosthetic types fabricated by the ADR (92% lower-limb prosthetics and 8% upper-limb prosthetics), using the weighted average, it was estimated that on average a 2.3 kg roll of 3D printing filament roll can yield 2.12 prosthetics. In the case of the traditional manufacturing center, the indirect costs were set to include administrative fees, one visit for measurements, the manufacturing of the device, one visit for fitting, the fixing of the device, and one visit for fitting and placing the device. In the case of the 3D printer-based center, the indirect costs would include one visit for measurements, the manufacturing of the device, and one visit for fitting and placing the device. Given that the precision of the 3D scanners mostly removes the need for fixing the socket and device dimensions, the indirect costs for the 3D printer-based center was estimated to be 7.5%, which was obtained by multiplying the traditional technology indirect costs by the difference in steps between the two methods. Lastly, it was estimated that every eight years the printers would need repair; this information was based on the lifespan of an older model that has been used at the HHH under conditions similar to the ones expected at this center. The repairs were estimated to be equivalent to half of the cost of a new printer to leave a margin, and on-site personnel should be able to perform these repairs. As seen in Table 3, the production and maintenance costs of a 3D printer-based center was estimated to be approximately \$16,000 per year.

Table 3. Estimated yearly production and maintenance costs for the 3D printer-based center with a fabrication of 347 devices. To estimate the materials cost per prosthetic, a weighted average was estimated based on the information regarding the percentage of upper- and lower-limb prosthetics fabricated at the ADR multiplied by their respective material requirements (Asociación Dominicana de Rehabilitación, 2020).

3D Printer-based Center	Amount	Unit Cost			Total Cost		
Yearly Production and Maintenance Costs							
Materials/prosthetic	347	\$	39.63	\$	13,753.03		
Indirect costs/prosthetic	347	\$	2.97	\$	1,031.48		
Repairs	0.3125	\$	3,000.00	\$	937.50		
Total Cost				\$	15,722.01		

Analysis Set-up

Based on the fundamentals of the CEA, a monetary comparison between the expenses associated with the two prosthetic manufacturing techniques will be conducted to determine if the 3D-based method is more economically viable. To properly assess the difference, the annual prosthetic yield for both methods will be set to the current ADR production, 347, as seen in Table 1,3. To reduce the impact of the set-up costs of the 3D printer-based center and provide a better long-term comparison of the methods, the study will be conducted over the span of 10 years. Based on the annual yield of devices and the span of the study, Equation 1 will be used for the comparison of methods. As mentioned earlier, a discount rate of 4.2% will be applied to the future yearly production and maintenance costs to bring the total expenditure over 10 years to the 2019 net present cost (NPC).

Set - up Costs + Production and Maintenance Costs = Total Prosthetic Production (1)

Analysis over the Span of 10 Years

Recalling that set-up costs were neglected for the traditional manufacturing center, during Year 0, only the 3D printer-based center will have expenses, which correspond to its set-up costs. Starting on Year 1, the only expenses will be the yearly production and maintenance costs. Assuming that

Year 1 is 2019, the discount rate will only be applied after Year 2 to properly convert the total 10-year expenses into the 2019 NPC. As seen in Table 4, over the span of 10 years, the expenses associated with the traditional manufacturing center would be approximately \$3.77 million, while those associated with the 3D printer-based center would be approximately \$0.16 million. Not only is there over an order of magnitude between the two values, but the total 10-year expenses for the 3D printer-based center are estimated to be lower than the expenses associated with the traditional manufacturing center for a single year.

Table 4. Estimated expenses associated with the traditional manufacturing center and the 3D printer-based center over the span of 10 years with a total production of 3470 devices each.

Year	Traditional Center		3D Printer-based Center		
Teal		Expenses	Expenses		
0	\$	-	\$	29,225.00	
1	\$	449,868.75	\$	15,722.01	
2	\$	431,777.28	\$	15,089.75	
3	\$	414,413.36	\$	14,482.91	
4	\$	397,747.73	\$	13,900.48	
5	\$	381,752.31	\$	13,341.47	
6	\$	366,400.14	\$	12,804.95	
7	\$	351,665.37	\$	12,290.00	
8	\$	337,523.15	\$	11,795.75	
9	\$	323,949.66	\$	11,321.39	
10	\$	310,922.02	\$	10,866.10	
Total 2019 NPC	\$	3,766,019.77	\$	160,839.80	

So, why are traditional prosthetics so costly in comparison to the 3D printed ones? Based on personal experience visiting both the HHH and ADR centers, the main difference in cost lies in the manufacturing process. For the manufacturing of a traditional prosthesis, prosthetists need to make measurements of the different body parts, paying special attention to the location of the relevant biological features, and a plaster cast is made around the stump to create a positive

replica of the limb. Upon obtaining the replica, a sheet of thermoplastic is placed in a high temperature (and very energy intensive) oven and is then vacuum formed around the positive replica, effectively creating a test mold. This process can take several hours or a day before the patient is required to return to the center for a first fitting. Using thermoplastic for the test fitting is beneficial so that if pressure points are present, it can generally be modified to fit the patient better. Depending on the type of prosthetic being fabricated, the fabrication process can use different methods and materials. Generally, the socket is made to measure for each patient and the main components are pre-ordered both locally and from abroad or fabricated at the center. Upon the fabrication and assembly of the device, the patient is fitted for the socket and the prosthetic. On occasions, the device does not fit properly and the process needs to be repeated. Thus, the main difference in unit cost between the two methods comes from the reduction in materials and equipment. Thermoplastic sheets and the high temperature oven are two components that increase the overall cost. Additionally, whereas most parts need to be purchased with the traditional method, 3D technologies enable the center to print most of the parts themselves, only being responsible to cover the charges for the raw materials.

Sensitivity and Breakeven Analyses

To complement and validate the results obtained from the CEA, two types of analyses were performed simultaneously and individually. The sensitivity analysis, which is the result of changing the value of a single variable at a time, was performed to determine the susceptibility to change of the results. The breakeven analysis was performed, when possible, to determine the point at which there would no longer be a positive net benefit. The latter was done by increasing or decreasing the value of a single variable at a time until the cost of both methods was equal. The variables tested were the cost per traditionally manufactured prosthetic, the cost per 3D printer-

based prosthetic, the prosthetic yield per 3D printing filament roll, the 3D printer cost and the discount rate as seen in Figures 3-7, respectively. It must be noted that like for the CEA, for this sub-section, the material cost of the 3D printed prosthetics was estimated by obtaining the weighted average between the lower-limb material costs and the upper-limb material cost at 92% and 8%, respectively, according with the current ADR fabrication distribution.

The cost per traditionally manufactured prosthetic was varied to simulate a scenario where the cost of a prosthetic using the traditional method decreased. For this portion of the analysis, the prosthesis cost for each method was defined as the sum of the materials and indirect costs. This variable seemed to play a significant effect on the total cost, with a breakeven at \$49.22 per device, which represents a 96% decrease from the original cost, as seen in Figure 3. The cost per 3D printer-based prosthetic was varied to simulate a scenario in which the cost of a prosthetic using this method increased. This variable appeared to have a limited effect on the total cost as the breakeven would occur at \$1,194.13, which represents a 2,703% increase from the original cost, as seen in Figure 4. The 3D printer cost, which affects the printer cost directly and the repair cost indirectly, was varied to simulate a scenario where the cost of a 3D printer increased. This variable also appeared to play a limited role in the total cost as the breakeven would not occur until the price increased by 15,779% at \$476,365.83 per printer, as seen in Figure 5. However, in the past few years, both the materials cost and the printer costs for the 3D printer-based method have decreased by 43% and 20%, respectively, rendering both breakeven targets even less probable.

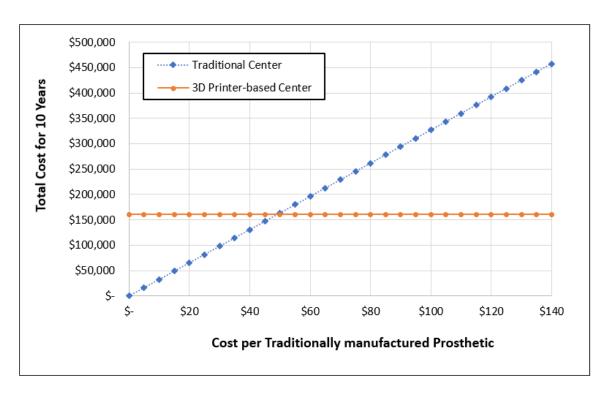


Figure 3. Sensitivity and breakeven analysis of the cost per traditionally manufactured prosthetic, comparing the total 10-year cost of the traditional center and the 3D printer-based center with a cross over at \$49.22 per device.

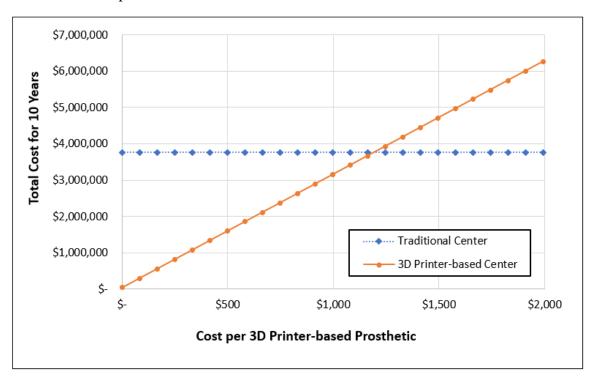


Figure 4. Sensitivity and breakeven analysis of the cost per 3D printer-based prosthetic, comparing the total 10-year cost of the traditional center and the 3D printer-based center with a cross over at \$1,194.13 per device.

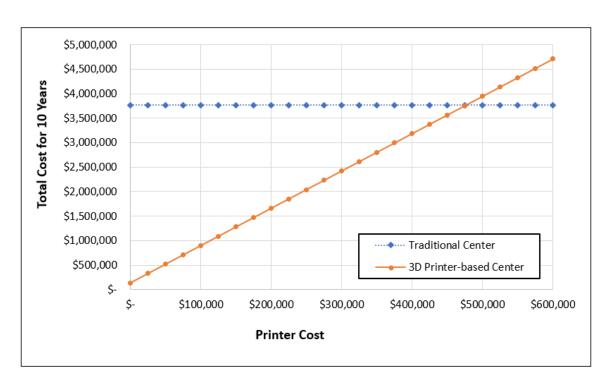


Figure 5. Sensitivity and breakeven analysis of the cost of a 3D printer, comparing the total 10-year cost of the traditional center and the 3D printer-based center with a cross over at \$476,365.83 per printer.

COVID-19 pandemic, the discount rate was studied at significantly different rates from 0-100%, as seen in Figure 6. As expected, considering that the costs associated with the 3D printer-based center are never higher than those of the traditional manufacturing center, increases in the discount rate approximated the costs of the centers but did not cause them to cross. The discount rate was the only variable tested for which a breakeven point could not be reached. Lastly, one of the most important variables testes was the prosthetic yield per 3D printing filament roll. As mentioned earlier, data regarding the prosthetic yield per roll for lower-limb prosthetic was not available, therefore an assumption was made regarding this value. As seen in Figure 7, the breakeven takes place at a yield of 0.07 devices per roll, which represents a 97% decrease from the estimated yield. This yield implies that 14.3 rolls, 33 kg of material, would be needed to print

a device. While a 97% decrease is among the lowest needed in the study for a breakeven to take place, the elevated weight of the device renders this scenario extremely improbable.

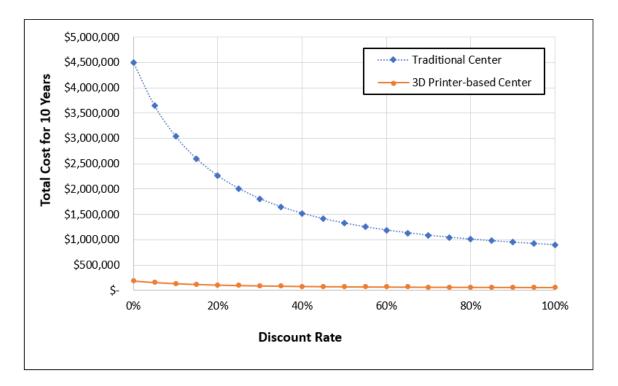


Figure 6. Sensitivity and breakeven analysis of the discount rate used in the study comparing the total 10-year cost of the traditional center and the 3D printer-based center.

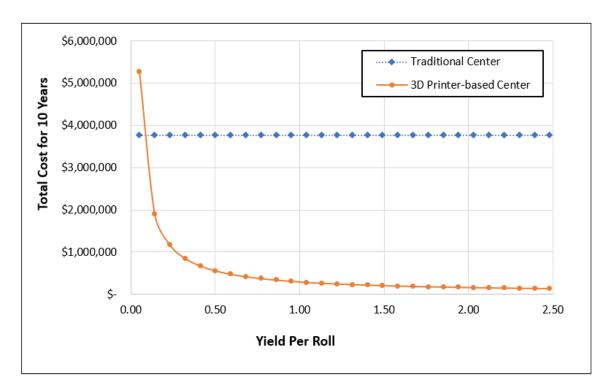


Figure 7. Sensitivity and breakeven analysis of prosthetic yield per 3D printing filament roll, comparing the total 10-year cost of the traditional center and the 3D printer-based center with a cross over at 0.07 devices per roll.

Based on the different factors tested, the results yielded by the CEA were most susceptible to changes in the cost per prosthetic using the traditional method and to the yield per 3D printing filament roll. However, considering that the price per prosthetic using the traditional method has not fluctuated significantly in the past decade, it is unlikely that the unit cost will see a 96% decrease. Similarly, considering the weight restraint of each device, a yield of 0.07 devices per roll does not seem probable; instead, it is more likely that a lower-limb device would require a more costly material rather than 97% more than an upper-limb prosthesis. An increase in material cost was also indirectly tested by the increase in cost per prosthetic using 3D printers; however, as mentioned earlier, the current cost would need to increase by over an order of magnitude for the breakeven to take place, which is also very unlikely. Therefore, considering the percentage by which each variable would have to change for a breakeven to occur, the analysis strongly suggests that regardless of fluctuations in the variables, the 3D printer-based method is an improvement

from the *status quo*. While it is difficult to properly determine how many prosthetics could be printed over a 10-year span with the current available budget considering space and personnel limitations, among others, neglecting these, about 48,580 devices could be fabricated using the 3D printer-based method. To estimate these values, it was assumed that the initial set-up and the yearly production and maintenance costs would only be able to yield 347 devices per year. Therefore, to obtain 48,580 devices in a 10-year span, the calculations were performed by estimating the costs of setting up 14 individual centers. While other factors need to be considered, the transportation barrier could be significantly decreased if these centers were distributed across the higher density cities across the country.

6.3 What would be the main challenges in the implementation of 3D printed prosthetics in the Dominican Republic?

Even when a technology seems sound and is economically viable, there can still be countless of non-technical factors that may interfere with its proper implementation. Research Question 3 aims to assess the main challenges that may arise in the implementation of 3D printed prosthetics in the Dominican Republic from a social and political context. Experts in the field Hinya De Peña and Guarocuya Félix were consulted for this purpose (De Peña, 2020; Félix, 2020). Additional information regarding the challenges from the social context were included from personal experience and literature.

De Peña suggests that the lack of a single centralized institution or effort responsible for the health care of amputees can be a challenge in providing care to amputees regardless of the technology being used (De Peña, 2020). People deep in the countryside, where functional illiteracy and marginal literacy are a real problem, have limited access to public information and are less aware of the protocol they should follow to address their medical needs. As a result, they will often have

to undergo a series of costly visits, bouncing between offices and sometimes provinces before learning about the process described in Section 6.1. Moreover, she suggests that the lack of clear government leader in the health care for amputees has also resulted in the lack of an information policy, which prevents the government from effectively communicating with the public and transmitting relevant health care information. This was also addressed in Section 6.1 through the tweet from Chanel Mateo Rosa, the director of the SNS, via his personal Twitter account.

Moreover, she suggests that limited education among the general public in the country presents a significant threat in the implementation of emerging technologies (De Peña, 2020). Local universities offer traditional careers such as civil engineering and medicine, while the more novel careers such as biotechnology and biomedical engineering are either in their early stages or are yet to be adopted by the universities. Additionally, despite recent improvements, a high percentage of public higher education scholarships are traditionally given to children of public officers or with governmental connections. As a result, the general population has limited access to both education and training in emerging fields.

Similarly, she suggests that a lack of technical information at the government level also provides a significant challenge in the implementation of novel technologies. Since the government usually provides job descriptions rather than requirements for most public officer positions, the public officers in charge of the decision-making process and their team may not have access to the information needed to assess the situation adequately. In the past, a civil engineer has served as the Minister of Education, a physician as the Vice Minister of Higher Education, and a lawyer as the Minister of the Environment, among many other examples (De Peña, 2020). The lack of national policies that require high-level officials to have technical background in the fields they represent combined with the general deficit in technology education in the country, government

officials do not have easy access to information regarding emerging technologies. As a result, traditional technologies tend to be favored to ensure their proper implementation despite the presence of more efficient technologies. Félix suggests that considering the significant reduction in cost, the lack of implementation of 3D technologies in the health field further supports the lack of technical information among the decision makers in the field. When government needs to make monetary allocations to address a need, they do so aware of the fact that they are choosing one need over another; however, he says that in a case like this one where additional resources are not required, the most beneficial decision is more evident.

Félix also suggests that a challenge that can prevent the implementation of technologies in the country, even when the education and information are present, is the intangible institutional costs. While CEAs and similar analyses attempt to put a monetary value into the components involved in the decision-making process, the cost of these intangible institutional components is not monetary. In this case, he suggests the main institutional cost is that of conviction. How much does it cost to put an issue in the agenda of the decision maker? How much does it cost to convince the decision maker that this is a good decision? This process would require the involvement of non-profit organizations or lobbyists, and the development of a study similar to this one to persuade the decision makers. Despite not necessarily representing a monetary value, for these events to take place, the initiative of the general public or the government officials is needed, going back to the limited education and information in the country. Thankfully, in this case, the gap created by the limited technical education and information is partly being filled by the ADR, who has already had the initiative to inquire about this emerging technology.

Félix also pointed out that the tributary system in the Dominican Republic, which exerts low pressure particularly among the rich, prevents the rapid progress of the country. The bulk of the

tax collection in the country comes from those of medium to low incomes, yet these populations are also the most affected by low-incomes and job instability. Thus, the low-taxation policies in the country leads to a feeble social security system, which in its turn leads to a feeble health care system. Therefore, despite generally aiming for a universal public health care system, the private health care system currently provides better care.

Lastly, based on literature and from personal experience contacting several experts in the field across different countries, another major challenge that affects the success of the implementation of the technology is its public acceptance. It is often observed that people will promptly form opinions about novel technologies despite the lack of availability of reliable data to support their position (Scheufele & Lewenstein, 2005). Therefore, it is important to place significant effort in assessing the preconception of both the user and the general population regarding prosthetic devices prior to its implementation as there appears to be a link between public acceptance and usage of the device. Considering that the success of a technology is typically be measured by its proper functioning, if the devices are not being used, then the technology is not addressing the need despite having the potential to do so. Thus, by performing an assessment prior to the implementation, the prosthetic offering of the center can be modified to address the needs of its society and increase the likelihood of usage. For instance, one solution that was determined for children in developed countries was to allow customizability of the limbs to match their favorite color or superhero (Kuehn, 2016). Unfortunately, the same does not apply to adults. Generally, the ideal prosthesis for adults and seniors, particularly in developing countries, are those that are the most unnoticeable. In fact, research in developed countries has determined that after functionality the aesthetic of the device is considered one of the most important determinants in the usage of prosthesis (ten Kate et al., 2017). Data from the field in developing countries has suggested that in countries with increased stigma around amputees and prosthetic devices, the aesthetic of the device might be the most important determinant. An advantage of 3D printed prosthetics as opposed to the traditionally manufactured devices is the ability to optimize the architecture of the device while compromising the appearance as little as possible through free-form 3D architecture, which allows to manufacture light, customizable devices (Ghosh et al., 2018).

7. DISCUSSION AND CONCLUSIONS

7.1 DISCUSSION

Based on the research conducted for the History of the National Medical and Social Infrastructures Section and on the findings presented in Section 6.1, the main barriers to health care for amputees in the Dominican Republic appear to be monetary and transportation. However, upon further inspection, these barriers were determined to be simply a manifestation of a more deeply rooted issue within the national infrastructure. A redundancy in government institutions overlooking the health care of amputees has resulted in a dilution of both responsibility and accountability. As a result, despite the limited prosthesis coverage from the government, there are no protocols or plans to develop a protocol to be followed by people in need of prosthetics.

To reduce both the monetary and transportation barriers resulting from the current system, 3D printer technologies were presented in Section 6.2 as an alternative technology for the fabrication of prostheses. Based on the analysis conducted in that section, the evidence suggests that a switch in technology would decrease the current spending by at least one order of magnitude. Moreover, the significant decrease in unit cost and operational cost would decrease the monetary barrier by making the devices more economically accessible. Similarly, it is believed that the reduction in total expenses resulting from the switch in technology would enable the opening of additional 3D

printer-based centers across the country without exceeding the current budget, effectively reducing the transportation barrier.

However, it must be stressed that the effects of a switch in technology to manufacture prosthetics from the traditional method to the 3D printer-based method would only address some of the issues currently affecting the prosthetic health care of amputees. In Section 6.1, the main issues were determined to be the redundancy in government institutions which leads to dissolved responsibility and accountability among them, the monetary and transportation barriers to health, the lack of a streamlined system for amputee healthcare, and the lack of an effective communication system. While the implementation of 3D technologies could significantly decrease the monetary and transportation barriers to health, the other issues would be unaffected by this change and would have to be addressed separately and, ideally, simultaneously.

Nonetheless, despite the economic viability of the 3D printing technology, additional issues are expected to arise during the implementation of emerging technologies; therefore, the implementation of 3D technologies for the manufacturing of prosthetics was also assessed from a social and political context. Based on the opinions of experts in the field, some of the major concerns are considered to be the lack of a proper communication system in the healthcare industry across the Dominican Republic, the lack of education and information in the field, the low-pressure tributary system, and the presence of intangible costs. Additionally, based on literature and personal experience, a major challenge that ought to be considered is the need for an assessment prior to the implementation of the technology to ensure usage of the device. Policy recommendations were developed to address some of the most pertinent issues brought to light in Section 6.3, which can be found in Section 7.3 below.

Based on the findings presented throughout the study, it is believed that due to a recent change in national sentiment surrounding people with disabilities accompanied by the economic viability of the technology, a switch in technologies would have a positive effect on society. This belief is further supported by the current position of the ADR, who has shown great interest in the technology and are in the early stages of adopting it for some of their protocols. The increased interest in 3D technologies from the ADR served as additional motivation for this study, as it would likely provide them with useful information in the areas of budget prediction and implementation.

7.2 HEALTH CARE SYSTEM MODEL: CANADA

Universal health care is considered the golden standard in most countries; however, few countries have successfully implemented it. In North America, the Canadian healthcare system is currently seen as a role model. Prior to adopting a universal system between the mid- to late 1900s, like in the Dominican Republic, most of the health care in Canada was privately funded and delivered (Government of Canada, 2019). Therefore, despite differences in governance types, considering the long-term success of the Canadian system, this model will be used to provide an example of a country whose universal healthcare system has shown great success.

In Canada, provincial and territorial governments are economically responsible for most healthcare expenditure, covering 71% of the expenses; however, the federal government provides them with significant financial support through fiscal transfers as represented by Figure 8 (Government of Canada, 2019). The Ministers of Health and Respective Departments play a crucial role in the organization and evaluation of the healthcare system with feedback from the Federal-Provincial-Territorial conferences and committees. While there are several more institutions involved in the Canadian healthcare system, the organizational chart represented by Figure 8 aims to highlight the

most relevant actors for the purpose of this study. Health Canada is the regulatory agency that ensures that the national standards for universal health coverage are met, and the Public Health Agency of Canada is responsible for public health response and preparedness, and health promotion (Tikkanen et al., 2020). And lastly, the Health Services and Providers, which are mostly self-governing, provide the services to the patients and receive most of their funding from the Provincial and Territorial governments with the exception of minor cost-sharing and out-of-pocket expenses. In 2010, the Canadian government spent an average \$5,450 USD per capita in healthcare whereas the Dominican government only dedicated \$580 USD per capita in 2014 (Government of Canada, 2019; World Health Organization, 2018). As a result, the government is able to provide universal healthcare for all Canadian residents and in some cases to refugees, protected persons, and refugee claimants. Nonetheless, 67% of the population is enrolled in a secondary health insurance, mostly through their employer, to cover the services that are not covered by the national health insurance such as vision care, dental care and outpatient prescription drugs (Tikkanen et al., 2020).

Considering that health care is primarily a provincial and territorial responsibility, the nature and percentage of coverage can vary greatly across the country. In the case of prosthetics, while two provinces do not have established regulations regarding prosthetic coverage and treatment is provided on a case-by-case basis, the remaining provinces provide coverage of 75-100% for both upper and lower limb prosthetics (Howard et al., 2020). The replacement interval ranges from 2-5 years depending on the province; however, three provinces do not have established regulations regarding the covered replacement frequency. Additionally, while the values mentioned above reflect the coverage of basic prosthetics, some provinces provide some coverage for myoelectric and microprocessor prosthetics (Howard et al., 2020).

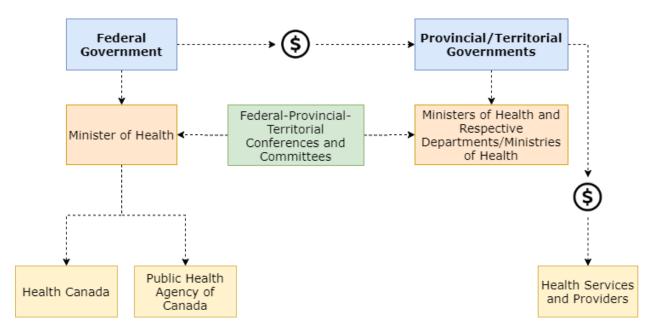


Figure 8. Diagram representation of the different organizations and institutions involved in the Canadian healthcare system (Tikkanen et al., 2020). The arrows represent their relationship to each other. Dashed lines were used to indicate autonomous institutions, and the "\$" sign was used to reflect funding.

The presence of a regulatory Agency such as Health Canada is one of the key components preventing the success of the Dominican healthcare system. Without having an agency performing evaluation assessments and ensuring that the needs of the population are being met to the national standard, it is difficult to assess how the system can be improved. The Federal-Provincial-Territorial conferences and committees create a feedback loop that provides crucial insight regarding the current state of the healthcare system. While converting the Dominican system into the Canadian system would be highly impractical considering the differences in governance, overlaps in the two systems would enable the Dominican Republic to borrow some of the Canadian policies. For instance, the Dominican Ministry of Health could develop a feedback system that allows them to evaluate the performance of the healthcare system, strengthen the regulatory responsibilities of some of the agencies involved in healthcare, encourage interstate conferences and committees, or review its current coverage of medical necessities.

7.3 POLICY AND IMPLEMENTATION RECOMMENDATIONS

As discussed in Section 6.1, the ADR has become the main advocate for amputee health care in the country; however, limited funding prevents the institution from fully addressing the needs of amputees. Consequently, significant monetary and transportation barriers have been created surrounding the prosthetic health care for amputees.

Recommendation One: Switch to a 3D Printer System

The elevated fabrication costs combined with poor coverage from SENASA only allow 6.5% of the estimated amputee population to obtain prostheses. Similarly, the elevated fabrication costs combined with the limited resources of the organization prevent prosthetic care from being offered outside of its main center in the capital. As a result, significant monetary and transportation barriers have been created around the prosthetic care in the country. However, Section 6.2 suggests that a switch in technology would decrease the prosthetic spending of the ADR and the unit cost, making it more economically accessible to people and reducing the monetary barrier. Similarly, given the reduced start-up costs and space requirement for the 3D-based centers, this technology opens the doors to the development of prosthesis care centers in more than one location across the country. Specifically, the current prosthesis spending could be used to increase the prosthesis fabrication from 347 devices in one location, to 4,858 devices per year at 14 different locations, almost meeting the national target. By strategically placing these centers in highly populated cities, or cities that have shown a higher incidence of amputations, the inclusion of these centers would significantly decrease the transportation barrier.

Recommendation Two: Streamline the Government Infrastructure

Nevertheless, while a switch in fabrication technology at the ADR could significantly decrease the barriers and challenges faced by amputees, the issue cannot be fully addressed without targeting

its root. Based on the findings brought to light in Section 6.1, from a political context, the source of the problem lies in the institutional redundancy and its consequent inefficiency in the social and medical infrastructure. Ideally, the government would streamline its infrastructure into a leaner system, increasing the efficiency of the government and allowing them to divert funds from administrative fees to services for the people. However, proposing modifications to the national infrastructure would be highly difficult and impractical. Therefore, a solution that involves both the ADR and the government was developed in an attempt to bypass the limitations presented by the sole leadership of the ADR and the difficulty in modifying the national infrastructure. Additionally, it is believed that without having to undergo major infrastructural changes, by borrowing elements of more efficient systems, such as the Canadian health care system, the Dominican Republic could further maximize the efficiency of its resources. Two of the main features that could be transferred over would be the presence of a feedback loop that provides information regarding the current state of the national healthcare to the government, and increasing the regulatory responsibility of agencies currently involved in the health care for amputees.

Recommendation Three: Develop a PPA

Inspired by the electricity industry in the country, it is believed that the most practical solution would be to develop a public-private alliance (PPA) between the ADR and the government. Generally speaking, a PPA is a contractual alliance between a government agency and a private entity, which allows the government to outsource the task of interest while still being part of the solution. While a very similar arrangement is currently in place, formalizing the agreement could solidify the voice of the ADR as the leader in the field, centralizing the responsibility in a single institution. Additionally, the creation of a PPA could provide the ADR with the governmental connections and resources needed to centralize the health care for amputees and develop a health

care protocol with the help of the hospitals. As a result, the number of amputations unsuitable for prosthetics could be reduced, and the processing of patients between the hospitals and the ADR could be expedited. Additionally, the official establishment of the ADR as the leader in the health care for amputees could also result in an improved communication system with the people. When there is a single united voice or institution in charge of distributing a message, the message can be received more effectively.

Recommendation Four: Create an Assessment Protocol

Alternatively, the development and implementation of a system that requires a periodic assessment of government institutions with respect to specific issues could potentially decrease the dilution in responsibility and accountability. This protocol could be developed by the Ministry of Public Health and would emphasize the responsibilities that were assigned to each institution upon their conception. These responsibilities could represent both the needs of the country as a whole as well as those of the different sub-populations across the country. It is believed that performing periodic assessments on the performance of the different instructions in addressing the needs of the population would effectively result in an increased institutional responsibility, accountability and performance. Rather than starting this assessment protocol from scratch, it is believed that basing it off protocols that are currently being implemented and have shown success, such as those performed by Health Canada, could speed up the development of the latter and increase its success.

Recommendation Five: Develop a Partnership between the ADR and an NGO with experience in the field

Another recommendation that was made during Section 6.2 was the partnership between the ADR and an NGO with vast experience in the field for the prosthetic center. Traditionally, when a country is not adequately prepared in a field, the rapid implementation of emerging technologies tends to have a short-lived success. Considering the present state in the country with limited

technology education and information, a partnership with a well-experienced NGO would facilitate the implementation, maintenance, and eventual transition to autonomy of the 3D printer-based prosthetic center. There are currently numerous NGOs whose goal is to assist in the development of an autonomous system in developing countries that will assist throughout the process from the planning phase onwards. Based on the experience of centers like the HHH, this model has proved to be the most successful over the years. Additionally, this collaboration with an experienced NGO could provide the country with additional time while its own prosthetists and other relevant workers are brought up to speed with the technology. To start, VHP and ECF could be contacted to create a collaboration considering their extensive experience in the field and in the region. While I was working on the project mentioned during Section 1.2, the inclusion of HHH in the collaboration was also proposed considering their geographic proximity and experience in the field. Rather than requiring a commute from the Canadian base of VHP and ECF, the inclusion of HHH could facilitate transportation and training of the personnel.

Recommendation Six: Promote Education in Emerging Fields

To maximize the use of the time created by a partnership with a well-experienced NGO, based on the findings discussed in Section 6.3, the government should address the need for technical education among the general public and information among the public officers. To do so, the government could provide incentives to higher education institutions for the adoption of emerging fields and promote an increase in transparency to better regulate how the Ministry of Education bases its scholarship requirements. To increase the access to information of high officers, the government could base their job offerings on requirements rather than descriptions. Alternatively, the government could enforce the requirement for people with technical expertise in the relevant

ministries to promote the adoption of novel technologies when they present more economically viable solutions.

Recommendation Seven: Integrate Higher Education Institutions to Process

Lastly, it is also highly recommended that this effort be accompanied by representatives from the higher education institutions in the country. In addition to providing crucial insight in the social context, like the recommended public acceptance assessment prior to the implementation or even after the implementation, the inclusion of higher education institutions can have several benefits. By including universities in the process, the technical education gap in the country could be reduced by exposing students and professors to new technologies in the field. Similarly, this new generation who has been exposed to emerging technologies could be the key in the long-term success of the implementation of new technologies. As a result, the social impact of this switch in technology would be increased.

Additional Benefits

It must be noted that while the emphasis of these recommendations is to address the prosthetic needs of amputees in the Dominican Republic, many of these recommendations would be beneficial to different underserved populations across the country. Some of the general recommendations, like the promotion of education and information, would have beneficial impacts in different fields. The more specific recommendations, like the establishment of the ADR as the official leader and developing a single national protocol for amputees, could have an indirect impact by developing a system that can be translated into different fields. Both the direct and indirect translation potential into different areas of the health care system across the country further increases the societal benefit of a thorough and well-rounded implementation. Therefore, it is believed that while 3D printed prosthetics can be used to address the prosthetic needs of amputees

from an economic perspective, this transition would have to be accompanied by policies that promote a political and social environment in which such an implementation can have a lasting effect.

7.4 LIMITATIONS AND FUTURE WORK

Some of the general limitations in this study are the limited resources, such as time and availability to travel to conduct additional interviews and expand the scope of the study. However, based on the available resources and the experience of the experts consulted for the different sections, it is believed that the main issues were addressed within the current scope. A major limitation in this proposal that is not fully addressed is the lack of a standardized procedure to 3D print lower limb prosthetics. While there are several research groups making advancements in the field, most of the information currently available relates to case studies. This is of great importance considering that approximately 92% of the prosthetics fabricated by the ADR are lower-limb (Asociación Dominicana de Rehabilitación, 2020). However, considering that in the case where the ADR is not able to fabricate fully 3D printed prosthetics, the drastic difference in cost between the two methods would still result in a significant decrease in overall cost if the ADR were to adopt a hybrid method. Nia Technologies Inc. provides an example of the benefits associated with a hybrid approach. One of the main reductions in cost across technologies comes from the fact that whereas with the traditional method most parts need to be purchased, 3D technologies enable the center to print some of the parts, only needing to cover the cost of the raw materials. Additionally, a greater reduction in operational cost could be observed at the ADR if they were to expand the use of 3D technologies to other areas within their workshop. Considering that prosthetics are one of the many devices they currently fabricate or offer, the economic impact could be significant. An area where 3D technologies have also shown great success, as briefly mentioned in the Literature Review, is

in orthotic devices such as knee braces. While it would have been interesting to expand this study to include the different applications 3D technologies could have at the ADR, time constraints and resource limitations did not allow for a more robust study.

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